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License No.	MD-31-025-04	Amendment No.	22	

CONDITIONS CONTINUED

- 17. Safety features of the irradiator (which includes but is not limited to entry control devices, intrusion detection devices, warning systems, source positioning indicators, and controller logic which governs any safety device or system) shall not be altered, modified, replaced, or in any way changed without written approval of the Department. The licensee shall immediately report to the Department by telephone or telegraph the failure of any safety feature (device, system, or circuit) of the irradiator. A written report of such failure shall be filed with the Department within 10 calendar days after the failure, describing the failure, conditions under which the failure occurred, the suspected cause(s) of the failure, and action taken or proposed to correct the failure and prevent recurrence.
- 18. After inspection by the Department of any modification, change, alteration, replacement, substitution, addition, or deletion made to the Dickerson-II irradiator by the licensee, the Department may require the licensee to make additional modifications, changes, etc. that the Department deems necessary to reduce the likelihood of failure, to enhance recovery if a malfunction or incident were to occur, or to enhance security, protection, safety, or warning of malfunction or intrusion.
- 19. The irradiator cell and labyrinths shall be visually checked by the operator and controlled by any additional administrative procedures that are necessary to assure that these areas are cleared of personnel prior to each use of the source.
- 20. The irradiator cell and labyrinths shall be surveyed using a physical radiation detection instrument to assure that prior to the first individual's entry into these areas after any use of the source, the radiation level from the source in these areas is below that at which it would be possible for an individual to receive a dose in excess of 100 millirem in any one hour.

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CONDITIONS CONTINUED

- 21. The irradiator shall be maintained such that all entry control and intrusion detection devices must be functioning properly prior to the initiation of any operation using the source. No operation shall be conducted unless these control devices are functioning properly, except those operations necessary to place the source in a safe condition or to repair the malfunctioning control(s).
- 22. The licensee is authorized to set the RAM 22 alarm point at 200 milliroentgens per hour or less. The RAM 22 shall accurately reflect the dose rate at the associated detector in the north labyrinth of the Dickerson II irradiator. Whenever the RAM 22 alarm point is exceeded, visible and audible warnings shall be automatically given in the operator console area, and other actions as defined by the licensed safety system logic shall be automatically initiated.
- 23. The licensee is required to include the controller program to include automatic signaling to ADT (or equivalent service) when the RAM 22 alarm set point is exceeded.

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CONDITIONS CONTINUED

24. Except as specifically provided otherwise by this license, the licensee shall possess and use radioactive material authorized by this license in accordance with statements representations, and procedures contained in:

Application dated June 12, 1987 with attachments:

- A. Appendix A, dated June 12, 1987, "Description of the Dickerson II Irradiator."
- B. Appendix C, dated June 12, 1987, "Administrative Controls."
- C. Appendix 4, Table 1, dated October 3, 1984, "Current Area Monitors."
- D. Appendix 5.1, Table 1, dated October 3, 1984, "Current Survey meters."
- E. Appendix 5.2, dated October 3, 1984, "TLD and Film Service Compenies."
- F. Operational Competence Item (OCI) # 2, dated 10/17/83: "Security."
- G. Operational Competence Item (OCI) # 3, Rev. 3 dated June, 1987: "Alarms."
- H. Operational Competence Item (OCI) # 4, dated October, 1985: "Radiation Area Monitors.
- I. Operational Competence Item (OCI) # 5, Rev. 3 dated June, 1987: "Telephone Instructions."
- J. Operational Competence Item (OCI) # 9, dated June 02, 1987: "General Facility Safety.
- K. Operational Competence Item (OCI) # 31, dated October, 1985: "Dickerson-I Operator Training Menual."
- L. Operational Competence Item (OCI) # 35, dated September, 1984: "Dickerson-1 Operator Training Manual."
- M. Operational Competence Item (OCI) # 36, dated October, 1985: "Dickerson-I System Description."
- N. Operational Competence Item (OCI) # 47, dated November, 1983: "Introduction to Radiation Theory, Units, and Effects."
- O. Operational Competence Item (OCI) # 63, dated November, 1983: "Review Information for Irradiator Operators and Trainees."
- P. Operational Competence Item (OCI) # 65, dated June, 1987: "Irradiator Safety for Maintenance Personnel."

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		FOR THE MARYLAND DEPARTMENT OF THE ENVIRONMENT	
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	•	RADIOLOGICAL HEALTH PROGRAM MANAGER I	



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MD-31-025-04

Amendment No.

22

CORRECTED COPY

CONDITIONS CONTINUED

- Q. Procedure R 1001, Revision 2, dated March 14, 1977: "Counting Procedures.
- R. Procedure R 1002, Revision 5, dated June 7, 1989: "Sampling Procedures."
- S. Procedure R 2006, Revision 1, dated February 17, 1977: "Leak Testing in the Pool"
- T. Procedure R 1007, Revision 5, dated April 25, 1991: "Radiation Detection Instruments Calibration Procedure."
- U. Procedure R 6012, Revision 3, dated June 21, 1990: "Procedure for Irradiator Processor Controller."
- V. Procedure R 7002, Revision 4, dated June 02, 1987: "Procedure for Dickerson II Irradiator Operator Qualification."
- W. Procedure R 7003, Revision 4, dated June 02, 1987: "General Procedure for Dickerson II Irradiator Operations."
- X. Procedure R 7004, Revision 3, dated January 26, 1993: "Procedure for Routine Dickerson II Maintenance."
- Y. Procedure R 7005, Revision 0, dated June 02, 1987: "Procedure for Non-Routine Maintenance of the Dickerson II Irradiator Requiring Temporary Defeating of a Safety System Component."
- Z. Procedure R 7006, Revision 3, dated June 12, 1987: "Procedure for Dickerson II Labyrinth Loader Qualifications and Operations."
- AA. Procedure R 7007, Revision 2, dated June 13, 1987: "Procedure for Source Changes and Additions to the Dickerson II Source Plaque."
- BB. Drawing 150368: "Modification of Operator 12 D-II", issued December 12, 1986 with letter dated December 17, 1986.
- CC. Drawing N150124: "Cable Cylinder Operator D-II", dated December 04, 1980. Drawing SK-19: "Layout and Study Conveyor Modification" with letter dated September 26, 1984.
- DD. Drawing 150098: "General Alignment Dickerson-II", dated July 12, 1984.

FOR THE MARYLAND DEPARTMENT OF THE ENVIRONMENT

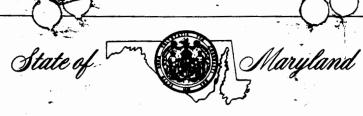
Date _____ March 14, 1996

RADIOLOGICAL HEALTH PROGRAM MANAGER II

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License No.

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CONDITIONS CONTINUED

- Q. Procedure R 1007, Revision 5, dated April 25, 1991: "Radiation Detection Instruments Calibration Procedure."
- R. Procedure R 6012, Revision 1, dated May 12, 1988: "Procedure for Irradiator Processor Controller."
- S. Procedure R 7002, Revision 4, dated June 02, 1987: "Procedure for Dickerson II Irradiator Operator Qualification."
- T. Procedure R 7003, Revision 4, dated June 02, 1987: "General Procedure for Dickerson II Irradiator Operations."
- U. Procedure R 7004, Revision 2, dated May 13, 1981: "Procedure for Routine Dickerson II Maintenance."
- V. Procedure R 7005, Revision 0, dated June 02, 1987: "Procedure for Non-Routine

 Maintenance of the Dickerson II Irradiator Requiring Temporary Defeating of a Safety
 System Component."
- W. Procedure R 7006, Revision 3, dated June 12, 1987: "Procedure for Dickerson II Labyrinth Loader Qualifications and Operations."
- X. Procedure R 7007, Revision 2, dated June 12, 1987: "Procedure for Source Changes and Additions to the Dickerson II Source Plaque."
- Y. Drawing 150368: "Modification of Operator 12 D-II", issued December 12, 1986 with letter dated December 17, 1986.
- Z. Drawing N150124: "Cable Cylinder Operator D-II", dated December 04, 1980. Drawing SK-19: "Layout and Study Conveyor Modification" with letter dated September 26, 1984.
- AA. Drawing 150098: "General Alignment Dickerson-II", dated July 12, 1984;

FOR THE MARYLAND DEPARTMENT OF THE ENVIRONMENT

Printed: October 16, 1995

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License No.	MD-31-025-05	Amendment No.

CORRECTED COPY

CONDITIONS CONTINUED

- A. Letter dated August 25, 1984
- B. Letter dated July 07, 1984 Re: Proposal to modify source changing mechanism.
- C. Letter dated April 16, 1984 with attached memorandums dated: March 26 & 27, 1984.
- D. Letter dated March 13, 1984.
- E. Letter dated November 10, 1984 with attached "Response Plan for Identifying and Isolating Leaking Dickerson-1 Irradiator Sources."
- F. Letter dated December 05, 1983 with OCI attachments.
- G. Letter dated September 30, 1983.
- H. Letter of April 07, 1983 outlining D-1 retrofit.
- I. Letter dated October 07, 1983.
- J. Letter of August 25, 1983.
- K. Procedure R 1001, Rev 2, dated March 14, 1977: "Counting Procedures."
- L. Procedure R 1002, Rev 5, dated June 7, 1989: "Sampling Procedures."
- M. Procedure R 1007, Rev 5, dated April 25, 1991: "Radiation Detection Instrument Calibration Procedures."
- N. Procedure R 2006, Rev 1, dated February 17, 1977: "Leak Testing in the Pool."
- O. Procedure R 6001, Rev 11, dated September 29, 1983: "General Procedure for Dickerson I Irradiator Operations."
- P. Procedure R 6002, Rev 2, dated August 23, 1983: "Procedure for Dickerson I Irradiator Operator Qualifications."
- Q. Procedure R 6003, Rev 7, dated February 01, 1989: "Procedure for Dickerson I Irradiator Maintenance."
- R. Procedure R 6005, Rev 6, dated October 2, 1991: "Dickerson I Source Changing Procedure."
- S. Procedure R 6006, Rev 2, dated September 29, 1983: "Source Loading Procedure."
- T. "Procedure for Response to On-Site Emergencies", dated June 6,/1983.

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Page 1 of ____ pages

Pursuant to the Maryland Radiation Act, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess and transfer radioactive material listed below; and to use such radioactive material for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules, regulations and orders of the Maryland State Department of the Environment, now or hereinafter in effect and to any conditions specified below. In accordance with Agency review, Radioactive Materials License

MD-31-025-05 is renewed in its entirety. CORRECTED COPY LICENSEE 3. License No. MD-31-025-05 1. Name Neutron Products, Inc. 4. Amendment No. 22301 Mt. Ephraim Road 12 (RENEWAL) P.O. Box 68 2. Address Dickerson, Maryland 20842-0068 5. Expiration Date November 31, 2000 7. Chemical and/or physical form 8. Maximum amount of radioactivity which 6. Radioactive material (element and mass licensee may possess at any one time number) A. Doubly encapsulated in A. 750,000 curies; A. Cobalt-60 stainless steel meeting No source to exceed 15,000 specifications described in curies. Products. Neutron Inc. letter dated August 25, 1983 with attachments; or Products, Neutron Inc. custom sealed sources which doubly have been encapsulated in accordance with Neutron Products, Inc. Procedure No. R5006, Revision O.

9. Authorized Use

For use in the water pool irradiator designated and known as "Dickerson I" for the irradiation of materials whose degree of flammability hazard does not exceed specifications 0, 1, or 2 of the National Fire Protection Association's <u>Fire Protection Guide on Hazardous Material</u> (latest edition), and which are not explosive.

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Page 1 of ____ pages

Pursuant to the Maryland Radiation Act, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess and transfer radioactive material listed below; and to use such radioactive material for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules, regulations and orders of the Maryland State Department of the Environment, now or hereinafter in effect and to any conditions specified below. In accordance with Agency review, Radioactive Materials License

MD-31-025-05 is renewed in its entirety. LICENSEE 3. License No. MD-31-025-051. Name Neutron Products, Inc. 4. Amendment No. 22301 Mt. Ephraim Road 2. Address P.O. Box 68 12 Dickerson, Maryland 20842-0068 5. Expiration Date November 31, 2000 7. Chemical and/or physical form 8. Maximum amount of radioactivity which 6. Radioactive material (element and mass licensee may possess at any one time number) A. Doubly encapsulated in A. 750,000 curies: Cobalt-60 stainless steel meeting No source to exceed 15,000 specifications described in curies. Neutron Products, Inc. letter dated August 1983 with attachments; or Products. Neutron Inc. custom sealed sources which have been doubly encapsulated in accordance with Neutron Products, Inc. Procedure No. R5006, Revision O.

9. Authorized Use

For use in the water pool irradiator designated and known as "Dickerson I" for the irradiation of materials whose degree of flammability hazard does not exceed specifications 0, 1, or 2 of the National Fire Protection Association's <u>Fire Protection Guide on Hazardous Material</u> (latest edition), and which are not explosive. Irradiation of food for human consumption is prohibited.



	RADIOA	CTIVE MATERIAL LICENSE
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		CONDITIONS CONTINUED
Radiation	" and Part J, "Notices,	provisions of Part D. "Standards for Protection Against Instructions and Reports to Workers; Inspections" of the "Regulations for Control of Ionizing Radiation".
3. Sealed so	urces containing radioac	ctive material shall not be opened.
	all times when the radio	only in modes where all entrance and/or exit doors remain oactive source is not in its shielded storage position in
> conducted	with the radiation sour m radiation levels in ea	rces in the irradiator, a radiation survey shall be rce loaded and in its up, operating position to determine ach area adjoining the radiation cell. Such surveys shall
	to the initiation of any dioactive source;	v irradiation of materials after the initial loading of
cell w		sterials (except empty product carriers) in the irradiator sherent shielding of the permanent physical structure of
curie	loading of the radioacti t total curie loading of	irradiation of materials after any increase in the total ive sources greater than ten (10%) above the previous fradioactive sources at which time a full survey was
		FOR THE MARYLAND DEPARTMENT OF THE ENVIRONMENT
Date		BADIOLOGICAL HEALTH PROGRAM MANAGER II

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CONDITIONS CONTINUED

A detailed report of the results of the surveys shall be sent to the Environmental Manager of the Radiological Health Program at 2500 Broening Highway, Baltimore, Maryland 21224 not later than twenty-five (25) days following initial installation of radioactive sources and following any increase greater than ten percent (10%) in the total curie loading of radioactive sources.

- 16. No physical radiation barriers of the irradiator (which includes but is not limited to all plugs and penetration shields) shall be removed, replaced, or modified in any manner without written approval of the Department.
- devices, warning systems, source positioning indicators, and controller and/or hardwired logic which governs any safety device or system) shall not be altered, modified, replaced, or in any way changed without written approval of the Department. The licensee shall immediately report to the Department by telephone or telegraph the failure of any safety feature (device, system, or circuit) of the irradiator. A written report of such failure shall be filed with the Department within 10 calendar days after the failure, describing the failure, conditions under which the failure occurred, the suspected cause(s) of the failure, and action taken or proposed to correct the failure and prevent recurrence.
- 18. After inspection by the Department of any modification, change, alteration, replacement, substitution, addition, or deletion made to the Dickerson-I (D-I) irradiator by the licensee, the Department may require the licensee to make additional modifications, changes, etc. that the Department deems necessary to reduce the likelihood of failure, to enhance recovery if a malfunction or incident were to occur, or to enhance security, protection, safety, or warning of malfunction or intrusion.

MARYLAND DEPARTMENT OF THE ENVIRONMENT
RADIOLOGICAL HEALTH PROGRAM MANAGER II

License No.

MD-31-025-05



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	c	CONDITIONS CONTINUED	

- 19. The irradiator cell and other inner chambers of the irradiator shall be visually checked by the operator and controlled by any additional administrative procedures that are necessary to assure that these areas are cleared of personnel prior to each use of the radioactive source.
- 20. The irradiator cell and other inner chambers of the irradiator shall be checked using a physical radiation detection instrument to assure that prior to the first individual's entry into these areas after any use of the radioactive source, the radiation level from the source in these areas is below that at which it would be possible for an individual to receive a dose in excess of 100 millirem in any one hour.
 - The irradiator shall be maintained such that all entry control and intrusion detection devices must be functioning properly prior to the initiation of any operation using the source. No operation shall be conducted unless these control devices are functioning properly, except those operations necessary to place the source in a safe condition or to repair the malfunctioning control(s).
- 22. The intermediate (source transfer) pool shall be kept filled with water to provide additional shielding from radioactive sources loaded in the Dickerson-1 irradiator pool.
- 23. The intermediate (source transfer) pool shall be used only for the transfer of sources into the Dickerson-1 irradiator.
- 24. Except as specifically provided otherwise by this license, the licensee shall possess and use radioactive material authorized by this license in accordance with statements

representations, and procedures contained in:				
	FOR THE MARYLAND DEPARTMENT OF THE ENVIRONMENT			
Date	RADIOLOGICAL HEALTH PROGRAM MANAGER II			



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Amendment No.

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CONDITIONS CONTINUED

- A. Letter dated August 25, 1984
- B. Letter dated July 07, 1984 Re: Proposal to modify source changing mechanism.
- C. Letter dated April 16, 1984 with attached memorandums dated: March 26 & 27, 1984.
- D. Letter dated March 13, 1984.
- Letter dated November 10, 1984 with attached "Response Plan for Identifying and Isolating Leaking Dickerson-1 Irradiator Sources."
- F. Letter dated December 05, 1983 with OCI attachments.
- G. Letter dated September 30, 1983.
- H. Letter of April 07, 1983 outlining D-1 retrofit.
- Letter dated October 07, 1983,
- J. Letter of August 25, 1983.
- K. Procedure R 1001, Rev 2, dated March 14, 1977: "Counting Procedures.
- L. Procedure R 1002, Rev 7, dated June 7, 1989: "Sampling Procedures."
- M. Procedure R 1007, Rev 5, dated April 25, 1991: "Radiation Detection Instrument Calibration Procedures."
- N. Procedure R 2006, Rev 1, dated February 17, 1977: "Leak Testing in the Pool."
- O. Procedure R 6001, Rev 11, dated September 29, 1983: "General Procedure for Dickerson I Irradiator Operations."
- P. Procedure R 6002, Rev 2, dated August 23, 1983: "Procedure for Dickerson I Irradiator" Operator Qualifications."
- Q. Procedure R 6003, Rev 7, dated February 01, 1989: "Procedure for Dickerson I Irradiator Maintenance."
- R. Procedure R 6005, Rev 4, dated September 29, 1983: "Dickerson I Source Changing Procedure.
- S. Procedure R 6006, Rev 2, dated September 29, 1983: "Source Loading Procedure."
- T. "Procedure for Response to On-Site Emergencies", dated June 6, 1983.

FOR THE MARYLAND DEPARTMENT OF THE ENVIRONMENT

RADIOLOGICAL HEALTH PROGRAM MANAGER II

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		CONDITIONS	CONTINUED			

- U. "Dickerson I, II Operators, Maintenance Checklist", date stamped August 26, 1983.
- V. "NPI Training Program", date stamped August 26, 1983.
- W. Drawings:
 - 1. A 1500361, dated June 29,1984: "Detector Shield RAM 17-Dickerson-1."
 - 2. B 150341, dated August 19, 1983: "Source Tree Loading Dickerson I."
 - 3. C 150336, dated August 22, 1983: "Bottom Guide Chimney Dickerson I Retrofit."
 - 4. D 150338, dated August 22, 1983: "Dickerson I Tank Dickerson I Retrofit."
 - 5. D 150326, Rev A, dated August 22, 1983: "Transfer Tank Dickerson I Retrofit."
 - 6. N 150329, dated August 22, 1983: "Assembly Source Transfer Mechanism-Dickerson I Retrofit."
 - 7. N 150331, dated August 22, 1983: "Source Baskets Mast Source Baskets Racks-Dickerson I Retrofit."
 - 8. N 150328, dated August 22, 1983: "Source Tree Coupling Transfer Tool-Dickerson I Retrofit."
 - 9. N 150327, dated August 22, 1983: "Source Tree Coupling-Dickerson I Retrofit."
 - 10. N 150332, dated August 22, 1983: "Retaining Caps-Source Trees-Dickerson I Retrofit."
 - 11. N 150337, dated August 22, 1983: "Details & Assembly Penetration Inserts-Dickerson I Retrofit."
 - 12. N 150330, dated August 22, 1983: "Details & Assembly-Source Down Sensor-Dickerson I Retrofit."
 - 13. N 150314, dated August 22, 1983: "Installation Elevation-Dickerson I Retrofit."
 - 14. D 150344, dated September 1, 1983: "Doorlock Cover & Pool Flashing-Dickerson I Retrofit."
 - 15. D 1500360, dated June 29, 1984: "Cable Stop Bracket Modification-Dickerson-1."
 - 16, C 120042, dated April 4, 1983: "Dickerson, Maryland Plant Location D-11."
 - 17. N 120052, dated April 4, 1983: "1st Floor Radiation Processing."
 - 18. N 150305, dated April 4, 1983: "Emergency Pull Cable System-Dickerson I Retrofit."

	FOR THE MARYLAND DEPARTMENT OF THE ENVIRONMENT			
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CONDITIONS CONTINUED

- 19. D 150319, dated March 31, 1983: "Electrical System-Dickerson I Retrofit."
- 20. D 150315, Rev B, dated June 21, 1982: "Safety Circuit-Dickerson I Retrofit."
- 21. D 150316, date stamped November, 1983: "PC I/O Dist.-Dickerson I."
- 22. D 150317, dated September 15, 1981: "Internal Wiring-Dickerson I."
- 23. D 150318, Rev B, dated September 13, 1983: "Power Supply-Dickerson I."
- 24. D 150319, dated March 31, 1983: "Electrical System-Dickerson I Retrofit."
- 25. D 150321, Rev A dated March 31 1983: "Pneumatics D-I Retrofit."
- 26. N 150320, Rev B, dated September 1, 1983: "General Arrangement-Retrofit Dickerson I."
- 27. D 150344, dated September 1, 1983: "Door Lock Cover & Pool Flashing Dickerson I Retrofit."
- 28. B 150341, dated August 22, 1983: "Source Tree Loading."
- 29. D 170227, dated March 31,1988: "Wall Safe Assembly K.I.S.S. Source."
- 30. S 120083, Rev. B dated August 08, 1986: "Site Plan."
- 31. N 120054, Rev. D dated August 11, 1986: "General Arrangement-Dickerson Facility"
- X. Dickerson I Daily Maintenance Checklist date stamped September 2, 1983.
- Y. Dickerson I Quarterly Maintenance Checklist date stamped September 2, 1983.
- Z. Dickerson I Daily Maintenance Checklist date stamped October 4, 1983.
- AA. Dickerson I Quarterly Maintenance Checklist date stamped October 4, 1983.
- BB. Dickerson I Processor Logic, dated September 30, 1983.
- CC. Addendum to September 1, 1983 Submission; dated September 2, 1983.
- DD. Technical Training Program, Rev 0, dated December 2, 1983:
 - 1. OCI #2, dated October 17, 1983: "Security."
 - 2. OCI #3, dated June 17, 1987: "Alarms."
 - 3. OCI #4, dated October, 1985: "Radiation Area Monitors."
 - 4. OCI #5, date stamped June, 1987: "Revised Telephone Instructions."
 - 5. OCI #9, dated June 2, 1989: "General Facility Safety."
 - OCI #31, dated October, 1985: "Dickerson I Operator Training Menual."

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License No.

MD-31-025-05

Amendment No.

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CONDITIONS CONTINUED

- 7. OCI #36, dated October, 1985: "Dickerson I System Description."
- 8. OCI #47, dated November, 1983: "Intro to Radiation Theory, Units and Effects."
- 9. OCI #62, dated November, 1983: "Introduction to Quality Assurance."
- 10. OCI #63, dated November, 1983: "Basic Information for Irradiator Operator Trainers."
- 11. OCI #65, dated June, 1987: "Irradiator Safety for Maintenance Personnel."
- EE. Transistorized Gamma alarm NMC Model GA-2TO, dated January 26,1979.
- FF. "Certification for Welding & Inspection", dated August 19, 1983.
- GG. "Welding Procedure Specifications for Welding Type 304 & 304L Stainless Steel by the Gas Tungsten Arc & Shielded Metal Arc Welding Process for D-1 Irradiator & Transfer Pools", dated August 23, 1983.
- HH. Memorandum dated August 22, 1983: "Ozone Generation in D-I."
- II. COMAR 26.12.01.01 "Regulations for Control of Ionizing Radiation" shall govern the licensee's statements in applications or letters, unless the statements are more restrictive than the regulations.

FOR THE MARYLAND DEPARTMENT OF THE ENVIRONMENT

Date printed: October 26, 1995

RADIOLOGICAL HEALTH PROGRAM MANAGER II

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REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES SAFETY EVALUATION OF SEALED SOURCE

NO.: MD474S105U

DATE:

April 05, 1971

PAGE 1 OF 2

SEALED SOURCE TYPE:

Teletherapy Sealed Source

MODEL: NPI XX-XXXX

MANUFACTURER/DISTRIBUTOR:

Neutron Products

P.O. Box 93

Dickerson, MD 20753

MANUFACTURER/DISTRIBUTOR:

ISOTOPE: Cobalt-60

MAXIMUM ACTIVITY:

LEAK TEST FREQUENCY:

PRINCIPAL USE:

Medical Teletherapy

CUSTOM SOURCE:

___ YES <u>X</u> NO

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES SAFETY EVALUATION OF SEALED SOURCE

NO.: MD474S105U

DATE:

April 05, 1971

PAGE 2 OF 2

SEALED SOURCE TYPE:

Teletherapy Sealed Source

DESCRIPTION:

Neutron Products, Inc., standard teletherapy sources are doubly-encapsulated in 304L stainless steel capsules and each capsule is sealed by tungsten, inert gas, arc welds. The maximum diameter of the doubly-encapsulated source is 1.260 inches with a maximum active core length of approximately 1.3 inches (3.4 centimeters). The wall thickness of the internal capsule varies from 0.050 to 0.312 inches depending upon the diameter of the cobalt-60 core. The bottom wall of the internal capsule is a minimum of 0.020 inch and the thickness of the welded cap is a minimum of 0.075 inch. The external capsule has a minimum of 0.045 wall thickness, 0.020 bottom thickness and 0.075 inch minimum cap thickness.

QUALITY ASSURANCE AND CONTROL:

The encapsulation is performed in compliance with NPI specifications P-4, dated January 11, 1971. The specifications define that at least three prototype welds shall be found to be free of voids and other defects by metallographic evaluations before the initiation of production welding for each different capsule. Leak testing is performed either through a helium pressure test, a helium mass spectrograph, the helium leak detector, or through vacuum testing. Surface contamination must meet 0.05 microcurie for the internal capsule and 0.005 microcurie for the external capsule.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

Upon delivery of a source for use in a teletherapy unit, the first two digits of the catalogue number designate the active diameter of the cobalt-60 in millimeters and the final digits will designate the dose rate in Roentgens/hour at one meter associated with the source.

ISSUING AGENCY:

Maryland State Department of Health and Mental Hygiene

SUMMARY OF MDE RECORDS ON ENFORCEMENT ACTIONS AND PERMIT ADJUDICATIONS WITH NEUTRON PRODUCTS

December 1973 to December 1974: contaminated water leaked from Neutron's storage canals and main pool and seeped into soil beneath the facility. A corrective order was issued to Neutron on July 31, 1975 requiring it to line the canals and main pool with stainless steel. Neutron complied.

November/December 11, 1980: a millicurie of cobalt-60, a significant and hazardous quantity of licensed radioactive material, was found in the public domain on the railroad tracks behind the Neutron facility. Neutron removed it.

June 20, 1986: the Department issued two administrative orders to Neutron regarding management and training deficiencies identified following an employee overexposure in the hot cell and the shipment of depleted uranium to a machine shop not authorized to possess radioactive material. In response to the employee overexposure, the Department identified management and training deficiencies and ordered training for all employees working in the hot cell. In response to Neutron's shipment of depleted uranium to the machine shop, the State ordered the clean up of the contaminated facility, the evaluation of personnel exposures, and other corrective actions. Neutron complied.

May 1988 to June 1988: On May 25, 1988, Frank Schwoerer, a Vice-President of Neutron, set off radiation monitors at the Rochester Gas and Electric Ginna Nuclear Power Plant in Ontario, New York. Mr. Schwoerer was found to be contaminated with Cobalt-60 as a result of routine activities conducted at the Neutron facility. Following the May 25, 1988 incident, the Department discovered Cobalt-60 in a secretary's personal vehicle, in employees' homes (in bedding, clothing, washing machines, and vacuum cleaners), and in unrestricted areas of the plant. The Department also found that food and beverages were being consumed in radioactive material contaminated areas, increasing the risk that employees would ingest radioactive material. On June 23, 1988, the Department, having determined that Neutron had inadequate equipment to evaluate personnel radioactive material (Cobalt-60) contamination, issued an administrative order to Neutron identifying violations and requiring certain remedial actions. Neutron complied.

January 1989 to June 1989: On January 27, 1989: the Department found that there was contamination in a former Neutron employee's home. On February, 1989, Mr. Schwoerer again set off radiation monitors at the Rochester Gas and Electric Ginna Nuclear Power Plant in Ontario, New York. Mr. Schwoerer was found to be contaminated with Cobalt-60 as a result of routine activities conducted at the Neutron facility. On March 3, 1989, MDE took emergency action to modify Neutron's license to manufacture sealed sources, limiting it to possession and storage only. On March 13 and 14, 1989, the United States Nuclear Regulatory Commission and the Maryland Department of the Environment jointly inspected the Neutron facility and operations and discovered that Neutron had lost control of Cobalt-60 because there was: a) radioactive material contamination of facility personnel; b) radioactive material contamination in unrestricted areas of the facility; and c) radioactive material contamination, through effluent releases, to unsecured Neutron properties outside

the facility and to adjacent railroad properties. On May 23, 1989, MDE issued Amendment #33 to Neutron's 01 license. This amendment outlined extensive changes required to correct deficiencies in Neutron's technical oversight specific to the control of the release of radioactive material to the public domain, training of occupational workers and overall management oversight of licensed activities. The amendment addressed; a) the acquisition of a state-of-the-art personnel contamination monitor; b) procedures for and training of personnel operating the monitor; c) the hiring of an independent health physics expert to evaluate facility problems; d) the establishment of a radioactive clean room; e) the establishment of a more comprehensive personnel training program; f) the establishment of a management random inspection program; g) the evaluation of radioactive material released to the community via wind borne release from the facility; h) the evaluation and clean up of radioactive material contaminated soils outside of the facility; and i) the evaluation and clean up of radioactive material in unrestricted areas of the facility. A hearing on the agency's action commenced in July 18, 1989 and a consent agreement was signed on July 25, 1989. The hearing was therefore discontinued and Neutron was allowed to resume normal operations.

October 30, 1989: the Department issued an order to modify Neutron's respiratory protection program because the Department considered it inadequate to protect the health and safety of Neutron's occupational workers. Key operations were suspended until the order was implemented. The order included requirements to assure the safe use of respiratory protection. Neutron complied.

November 9, 1990 and December 6, 1990: the Department issued to Neutron notices of violations, indicating numerous regulatory violations, and a failure to fully implement portions of amendment #33. These alleged violations included: occupational overexposure; multiple significant and willful violations of amendment #33; violations of reporting requirements; violations of license procedures; storage of licensed radioactive material at an unauthorized facility; and exceeding its possession limit for the specifically licensed radioactive material depleted uranium. After Neutron failed to correct these violations, the Department filed Civil No. 76639 in Montgomery County Circuit Court in 1991. On December 29, 1993, Judge Pincus of the Circuit Court issued a Memorandum Opinion and Order granting summary judgment on 17 counts, finding 5,820 violations. The Court also ordered Neutron to comply with Amendment 33 requirements and depleted uranium possession limits. In January of 1994, Civil No. 76639 was resolved by a Stipulation and Settlement. This agreement provided that Neutron pay the Department \$75, 000 and pay an additional \$125,000 if it failed to perform certain conditions.

January of 1996: Neutron's 01 manufacturing license was renewed by the Department. Neutron requested a contested case hearing on the new license. An administrative hearing was held in October 1997 and February 1998 and a proposed decision was issued on June 26, 1998 in which Administrative Law Judge Judith Finn Plymyer upheld the license as written by MDE. Exceptions were taken by Neutron on August 10, 1998 and the Department issued a final decision on August 24, 1999. Neutron appealed the decision fut did not seek a stay from the Circuit Court for Montgomery County.

September 1996 to February 1999: As a result of inspections occurring in 1997, 1998, and 1999, the Department has brought two administrative penalty actions. OAH #99-MDE-ARMA-047-004 was brought for violations identified with the 01manufacturing license. These included the failure to: a) conduct management audits in accordance with amendment 33 requirements; b) maintain appropriate written historical documentation pursuant to decommissioning requirements; c) secure licensed radioactive material to prevent unauthorized removal; and e) appropriately label licensed radioactive material. OAH #99-MDE-ARMA-047-239 was brought for violations identified with the irradiators operated under Neutron's 04 and 05 licenses. The violations alleged included delays in the installation of required fire suppression systems, an operator deliberately bypassing an irradiator safety system, failure to calibrate safety equipment at the license-required frequency and failure of operators to follow licensed irradiator operating procedures. Summary judgment was granted as to liability for a total of 3617 violations on February 15, 2000. Hearing in these consolidated actions will be April 3, 2000.

June 25-26, 1998: A radiation occupational overexposure occurred as a result of a failure of Neutron employees to conduct required radiation surveys and follow established license procedures. The Department brought administrative penalty action #99-MDE-ARMA-047-357 for these alleged violations, which are identified with Neutron's 03 teletherapy servicing license. A hearing is now scheduled for June 12, 2000.

November 9, 1999: Judge Nelson Rupp of the Circuit Court for Montgomery County granted summary judgment as to liability in <u>State of Maryland v. Neutron Products</u>, Case No.199036, finding that Neutron products had failed to comply with Maryland's financial assurance requirements for decommissioning. A trial on MDE's complaint for permanent injunctive relief is scheduled for September 2000.

January 1985 to present: the Radiological Health Program has conducted approximately 43 inspections and 20 investigations of Neutron Products.

1989 through 1996: approximately 150 radioactive particles of Cobalt-60 were found within one kilometer of the Neutron plant.

March 4th and 5th, 1999: A MDE inspection of the NPI facility (teletherapy servicing license) identified violations in the areas of failure to maintain adequate inventory of depleted uranium, failure, failure to adequately label radioactive material, failure to label an area containing radioactive material, failure to conduct annual review of radiation safety program, failure to conduct leak test of all sealed radioactive material sources, failure to evaluate overall yearly occupational doses for two teletherapy engineers and failure to maintain all calibration records for self-reading dosimeters (SRDs) for teletherapy engineers.

March 16, 18, and 19, 1999: A MDE inspection oft the NPI facility (manufacturing license) identified violations in the areas of failure to clean up radioactive contaminated soils, failure to maintain public dose ALARA, failure to adequately survey and clean up radioactive material debris in courtyard, failure to submit all monthly Health Physics Consultant reports to MDE, failure to conduct all monthly unrestricted floor surveys, failure to conduct all monthly random inspection surveys of the LAA, failure to conduct all monthly one kilometer radioactive material contamination surveys of community residents, failure to conduct all required leak tests for sealed sources and failure to comply with the 500 mRem facility boundary license criteria.

November 16, 18 and 19, 1999: MDE inspection of the NPI facility identified additional violations in the areas of failure to have all occupational workers attend required training sessions, failure to conduct adequate radiation surveys to define contamination off sight, failure to cleanup radioactive contaminated soils, failure to submit adequate radioactive material waste disposal plan, and failure to have an written emergency procedure for response to an abnormal water loss from an irradiator.